AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 09/732,241

Filing Date: December 7, 2000

Title: THERAPEUTIC CARBAMATES

Page 2 Dkt: 1343.011US1

claim 22.

Finally, it is acceptable for a claim to reference a table in the specification when it is more concise to incorporate the table by reference. Please see M.P.E.P. §2173.05(s); as well as *In re Faust* (Dec. of Superv. Exam. 1943) 86 USPQ 114; *Ex parte Maya et al.*, 156 USPQ 428; and *Ex parte Moon*, 224 USPQ 519, which were discussed at page 14 of the previous amendment and response filed 07 February 2002. For the above reasons, Applicant respectfully submits that claim 22 meets the requirements of 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection of claim 22 is requested.

Claims 48 and 49 were rejected under 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed.

The Examiner has the initial burden to provide evidence to support a rejection under 35 U.S.C. §112, first paragraph. M.P.E.P. § 2164.04. A specification that contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patent must be taken as being in compliance with the enablement requirement . . . unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. M.P.E.P. § 2164.04.

The specification discloses that compounds of formula (I) are useful in the treatment and prevention of diseases mediated by muscarinic receptors (page 3, lines 2-10). The Examiner has not provided any evidence or reasoning to question the accuracy of this statement. It is respectfully submitted that the Examiner's conclusion that "the specification does not provide enablement for the vast range of compounds encompassed by claims 1 and 2" is not supported by any evidence or reasoning. Additionally, the Examiner's conclusion at page 2 of the Office Action that "the compounds are structurally unrelated and would not be expected to have the same utility," is similarly unsupported, and inaccurate. The compounds recited by claims 48 and 49 possess a specifically recited group  $L_1$ , a linker X, and an amine containing group  $L_2$  that combine to provide a compound that binds to the muscarinic receptor. Thus, the compounds are not structurally unrelated as suggested by the Examiner. Additionally, claims 48 and 49 recite "a

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Page 3 Dkt: 1343.011US1

therapeutically effective amount," which, in effect, excludes any inoperative compounds. In light of the above comments, it is submitted that the Examiner has not met the burden required to establish a rejection under 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-52 were again rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record. This rejection is respectfully traversed.

The Examiner has the initial burden to provide evidence to support a rejection under 35 U.S.C. §112, first paragraph. M.P.E.P. § 2164.04. Again the Examiner has not met this burden. At page 2 of the Office Action the Examiner stated that "the structurally unrelated nature of the compounds recited in claim 1, e.g., pyridine vs. crown ether, is such that a reference anticipating one would not render the others analogously obvious for the same use." It is respectfully submitted that this is not the appropriate legal standard to establish a *prima facie* case of lack of enablement.

To establish a *prima facie* case of lack of enablement, the Examiner must provide reason to doubt the objective truth of the statements in the specification relied on for enabling support. M.P.E.P. § 2164.04. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. M.P.E.P. § 2164.04. The analysis and conclusion of lack of enablement should be based on the factors discussed in M.P.E.P. §2164.01(a) (the *Wands* factors).

The Examiner has provided no objective evidence or reasoned argument to doubt the truth of the statements at page 3, lines 2-10 of the specification. In view of this failure to establish a *prima facie* case of lack of enablement, withdrawal of the rejection of claims 1-52 under 35 U.S.C. § 112, first paragraph, is appropriate.

At pages 15 and 16 of the previous amendment and response filed 07 February 2002, Applicant provided a reasoned analysis regarding compliance of the instant claims with the requirements of 35 § 112, first paragraph, using the *Wands* factors. The Examiner did not address or rebut any of the points made by Applicant. If the Examiner maintains the rejection, Applicant respectfully requests that the Examiner provide specific findings of fact, supported by

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Page 4 Dkt: 1343.011US1

evidence, to support the rejection. Applicant also requests that the Examiner address the points made by Applicant in the previous *Wands* analysis, if the rejection is not withdrawn.

## Conclusion

Applicant respectfully submits that claims 1-52 are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-359-3265) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this day of \_\_\_\_\_\_\_, 2002\_\_\_\_\_\_, 2002\_\_\_\_\_\_

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Signature